

EPA Registration No.  
11556-131  
Vol. 3

# Material Sent for Data Extraction

Reg. No. 11556-131

Description: M. F. A.

☒ Materials(s) sent to Data Extraction Contractors:

☐ Newly stamped accepted label dated: \_\_\_\_\_

☒ Notification dated: 14 OCT 15

☒ New CSF dated: PAGE 1 AH I - AH 2 28 AUG 15

☒ Other: 12/15 1 DEC 15

☐ Decision #: 510445

☐ Other Action/Comments: \_\_\_\_\_

File this coversheet and attach materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the Jacket with the coversheet and materials inside, to Staff in the Information Services Center (ISC) (Room S-4900) or place in the designated bin. If the Jacket is full or only available as an image, please file materials in a new Jacket cover and follow the same procedure as above. For further information, please call 703 605 0716

Reviewer: Mark Dow

Phone: 305-5533 - - - Registration Division

Date: 1 DEC 15



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION

PREVENTION

01 DECEMBER 2015

Mr. J. Todd Frank  
Regulatory Affairs Consultant  
Bayer HealthCare LLC  
P.O. Box 390  
Shawnee Mission, KS 66201-0390

SUBJECT: Minor Formulation Amendment per PRN 98-10  
Product Name: CyLence Ultra Insecticide Cattle Ear Tag  
EPA Registration Number: 11556-131  
Application Date: 14 October 2015  
Decision Number: 510445

Dear Mr. Frank,

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated 14 OCTOBER 2015 for **EPA Registration 11556-131**. The Registration Division (RD) has conducted a review of the Confidential Statements of Formula (CSF), for the revised Basic Formulation, revised Alternate Formulation 1 and revised Alternate Formulation 2 submitted with this request for its applicability under PRN 98-10 and finds that the changes requested fall within the scope of PRN 98-10. Therefore, the revised Basic Formulation, revised Alternate Formulation 1 and revised Alternate Formulation 2 dated 28 AUGUST 2015 **are acceptable**. Copies of the respective CSFs have been added to the registration file for the subject product.

Please note that the record for this product currently contains the following CSFs:  
Basic CSF dated 28 AUGUST 2015  
Alternate 1 CSF dated 28 AUGUST 2015  
Alternate 2 CSF dated 28 AUGUST 2015

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, please contact me via telephone at 703-3-5-5533 or e-mail ([dow.mark@epa.gov](mailto:dow.mark@epa.gov)).

Sincerely,

Mark I. Dow, Ph.D.  
Chemistry, Inerts & Toxicology Assessment Branch (CITAB)  
Registration Division (7505P)  
Office of Chemical Safety and Pollution Prevention

D-# 510445

Bayer HealthCare



Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

2083

Attention: Jennifer Urbanski, Team 4

Subject: **CyLence Ultra Insecticide Cattle Ear Tag**  
**EPA Reg. No. 11556-131**  
**Application for Notification**

Dear Ms. Urbanski,

October 14, 2015

Bayer HealthCare LLC Animal Health is submitting an application to revise the Basic and ~~three~~ <sup>two</sup> Alternate CSFs on file for the subject product via Notification.

In support of this application, we are submitting the following documentation:

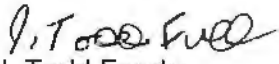
1. EPA Form 8570-1, with Confidential Explanation Page
2. 2 copies each of EPA Form 8570-4 -- Confidential Statement of Formula (CSF) for Basic Formulation dated 08/28/2015.
3. 2 copies each of EPA Form 8570-4 -- Confidential Statement of Formulas (CSFs) for Alternate 1, & Alternate 2 Formulation's dated 08/28/2015.
4. 1 copy of the most recent approved Basic, Alternate 1, & Alternate 2. CSFs all dated 03/07/2014.

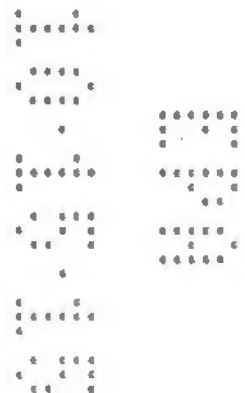
Bayer HealthCare LLC  
P.O. Box 390  
Shawnee Mission, KS  
66201-0390

Should you have any questions regarding this submission, please call me at (913) 268-2585 or email [todd.frank@bayer.com](mailto:todd.frank@bayer.com).

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Regards,

  
J. Todd Frank  
Regulatory Affairs Consultant





United States  
Environmental Protection Agency  
Washington, DC 20460

Registration  
Amendment  
☒ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 11556-131	2. EPA Product Manager Jennifer Urbanski	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) CyLence Ultra Insecticide Cattle Ear Tag	PM# Team Number 4	
5. Name and Address of Applicant (Include ZIP Code) Bayer HealthCare LLC, Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification per PR Notice 98-10:

See attached Explanation page.

E-mail Contact: todd.frank@bayer.com

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container	<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name J. Todd Frank	Title Reg. Affairs Consultant	Telephone No. (Include Area Code) 913-268-2585
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		5. Date Application Received (Stamped)
2. Signature <i>J. Todd Frank</i>	3. Title Regulatory Affairs Consultant	
4. Typed Name J. Todd Frank	5. Date 10/14/2015	



# Material Sent for Data Extraction

Reg. # 11556-131

Description: \_\_\_\_\_

☒ Material(s) Sent to Data Extraction Contractors:

☐ New Stamped Label Dated \_\_\_\_\_

☐ Notification Dated \_\_\_\_\_

☒ New CSF(s) Dated Basic and Alternates (and 3/7/14

☐ Other: \_\_\_\_\_

☐ Decision #: \_\_\_\_\_

☐ Other Action/Comments: \_\_\_\_\_

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: S. Hobgood

Phone: 703/308-8893 Division: RD

Date: July 2014



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

July 2, 2014

Mr. J. Todd Frank  
Regulatory Affairs Consultant  
BAYER HEALTHCARE LLC,  
Animal Health Division  
P. O. Box 390  
Shawnee Mission, KS 66201-0390

Subject: CSF Notification  
Decision #492167

Dear Mr. Frank:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated 6/9/14 for **EPA Registration 11556-131**. The Registration Division (RD) has conducted a review of four Confidential Statements of Formula (CSF) submitted with this request for applicability under PRN 98-10 and finds that the requested change(s) to: change the producer to a single point of contact; update the name/address of the a.i. source due to a company transfer and an inert supplier; and add an alternate a.i. source and inert supplier falls within the scope of PRN 98-10. Therefore, the revised Basic, Alternate 1, and 2 CSFs dated 3/7/14 **are acceptable**. A copy of each CSF has been added to the registration file for the subject product.

If you have any questions, please contact me directly at 703-305-0120 or the reviewer, Sherada Hobgood, at 703-308-8893 or e-mail: Hobgood.Sherada@epa.gov.

Sincerely,

/s/

Mark E. Suarez  
Risk Manager 13  
Insecticide Branch  
Registration Division (7505P)





United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 11556-131	2. EPA Product Manager Mark Suarez	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) CyLence Ultra Insecticide Cattle Ear Tag	PM# Team Number 13	
5. Name and Address of Applicant (Include ZIP Code) Bayer HealthCare LLC, Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201-0390 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification per PR Notice 98-10:  
See attached Explanation page.

E-mail Contact: todd.frank@bayer.com

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
* Certification must be submitted				<input type="checkbox"/> Plastic	
If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container	<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name J. Todd Frank	Title Reg. Affairs Consultant	Telephone No. (Include Area Code) 913-268-2585	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Affairs Consultant		
4. Typed Name J. Todd Frank	5. Date 06/09/2014		

# Bayer HealthCare

## Animal Health



Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

Attention: Mark Suarez, Team 13

Subject: **CyLence Ultra Insecticide Cattle Ear Tag**  
**EPA Reg. No. 11556-131**  
**Application for Notification**

Dear Mr. Suarez,

**June 9, 2014**

Bayer HealthCare LLC Animal Health is submitting an application to revise the Basic CSF on file for the subject product via Notification.

Bayer HealthCare LLC  
Animal Health  
P.O. Box 390  
Shawnee Mission, KS 66201

In support of this application, we are submitting the following documentation:

1. EPA Form 8570-1, with Confidential Explanation Page
2. 2 copies each of EPA Form 8570-4 -- Confidential Statements of Formula (CSFs) for Basic and Alternate (Alt. 1 and Alt. 2) Formulation's dated 03/07/2014.
3. 1 copy of the most recent approved Basic and Alternate (Alt. 1 and Alt. 2) CSF's dated 01/16/2012.

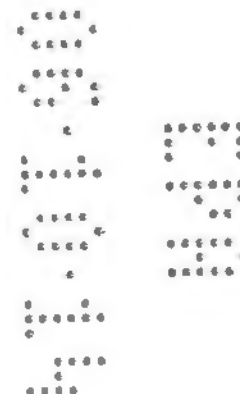
Should you have any questions regarding this submission, please call me at (913) 268-2585 or email [todd.frank@bayer.com](mailto:todd.frank@bayer.com).

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Regards,

J. Todd Frank

Regulatory Affairs Consultant





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS  
REGISTRATION DIVISION (7505P)

**DATE OUT:** June 28, 2012

**SUBJECT:** Storage Stability and Corrosion Study - Product Chemistry Review

**FROM:** Bruce Kitchens / Shyam Mathur  
Product Chemistry Team  
Technical Review Branch / Registration Division (7505P)

*Bruce Kitchens 6/28/12*  
*SBM 6/28/12*

**TO:** Dani Daniel / Venus Eagle  
Olga Odiott / Richard Gebken  
Rosanna Louie / Mark Suarez  
Melody Banks / Richard Gebken  
Registration Division (7505P)

**Company Name / Number:** BAYER HEALTHCARE LLC / 11556

**INTRODUCTION:**

In support of previous applications, the company / applicant has submitted the one year Storage Stability and Corrosion Characteristics studies for the following products:

PM	Reg. No.	DP Barcode	Decision No.	MRID No.	PC Code
01	11556-125	378289	433954	480964-01	129099; 129032
01	11556-127	378284	433956	480964-01	129099; 129032
01	11556-128	378285	433952	480964-01	129099; 129032
01	11556-130	378293	433957	480964-01	129099; 129032
13	11556-131	370264	420374	478509-01	067501; 118831
13	11556-141	385157	443564	482937-01	109701; 129032; 129099
13	11556-142	385158	443565	482937-01	109701; 129032; 129099
13	11556-143	385161	443566	482937-01	109701; 129032; 129099
13	11556-144	385162	443567	482937-01	109701; 129032; 129099
01	11556-153	401047	463759	487832-01	129099
10	11556-154	401459	464140	487910-01	036007

**SUMMARY OF FINDINGS:**

The Technical Review Branch has performed a fast track review of the associated products and concludes all of the studies are "acceptable". No products exhibited degradation of the active ingredient(s) in the products or corrosion of the packing material were observed during the period of testing.

